SHOTWELL & CARR, INC. SERVING THE FDA/EPA/USDA REGULATED INDUSTRIES SINCE 1974

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April 30, 2002

SUITABILITY PETITION

Dockets Management Branch
HFA-305, Room 1061
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

RE: Suitability Petition

Dear Sir/Madam:

Enclosed are four copies of a suitability petition we are filing on behalf of Richdel, Inc. Moundhouse, NV. The petition requests the Commissioner to permit Richdel to file an abbreviated new animal drug application (ANADA) for ivermectin having a different dosage form (oral gel) than that of the listed approved new animal drug (Eqvalan® Paste, Merial, NADA 134-314).

We point out that although Merial is codified as the sponsor or Eqvalan, all Eqvalan labeling currently available in the market appears to retain the originally approved sponsor name of Merck. Thus, the enclosed pioneer labeling reflects Merck as the sponsor. We trust this will be acceptable.

Please do not hesitate to contact us if additional information is required at this time.

Sincerely,

Mark L. Shepard, M.S.
Vice President

Enclosure

Cc: Richdel, Inc.

MLS:jdz

02P-0198

CP1

SUITABILITY PETITION

Petition Filed By:
Richdel, Inc.
23 Industrial Parkway
Moundhouse, NV 89706

Proposed Product:
Oral Gel Form
of Ivermectin for Horses

Date: April 30, 2002

Richdel, Inc.
Animal Health Products

SUITABILITY PETITION

The undersigned submits this petition under 512(n)(3) of the Federal Food, Drug, and Cosmetic Act, to request that the Commissioner of Food and Drugs permit Richdel, Inc. to file an abbreviated new animal drug application having a dosage form which differs from that of the listed approved new animal drug.

Name: Richard A. Merriner Date: 4/29/02

Richard A. Merriner

Title: President

23 Industrial Parkway, Moundhouse, NV 89706 • P.O. Box 1968, Carson City, NV 89702
Phone (775) 246-3022 • Toll Free (800) 648-0950 • Fax (775) 246-3324

I. Action Requested

The requested action is for the Commissioner to permit the filing of an abbreviated new animal drug application (ANADA) for our proposed product which differs from the approved pioneer product as follows:

Pioneer Product (Reference Drug)

Eqvalan® (ivermectin) Paste 1.87%, NADA 134-314, originally approved by the Center for Veterinary Medicine on May 29, 1984, and sponsored by Merial Ltd., is an oral paste indicated for the treatment of large and small strongyles, pinworms, ascarids, hairworms, large-mouth stomach worms, bots, lungworms, intestinal threadworms, and summer sores in horses. It is offered in an oral paste formulation containing 1.87% ivermectin. The paste is administered via an oral syringe having a plunger calibrated for administering doses sufficient to treat animal body weight increments of 250 lb., up to 1250 lb.

Proposed Product

The proposed product is an oral gel containing 1.87% ivermectin, which will be indicated for use in horses for the same claim(s) and will utilize the same incremental oral dosage directions as the pioneer product. Syringes of the proposed gel are individually packaged with one syringe per box. Each syringe plunger increment will treat 250 lbs. of body weight, up to 1250 lbs.

II. Statement of Grounds

The legal basis under which this application proceeds is as promulgated in the FD&C Act which allows the Commissioner to accept a generic drug application for an animal drug product which differs in dosage form from the pioneer or reference drug product. The dosage form for the proposed generic product described in this petition is similar to that of the pioneer drug in that both products are oral dosage forms. The difference is that this proposed generic product is in an oral gel whereas the pioneer drug is an oral paste.

The petitioner is not aware of any information, which would be unfavorable to the granting of the requested action.

III. Environmental Impact

Richdel, Inc. hereby requests a categorical exclusion from the requirements of preparing an environmental assessment based on 21 CFR 25.30(h). This subparagraph provides for categorical exclusions for actions such as the issuance, amendment, or revocation of procedural or administrative regulations and guidelines, including procedures for submission of applications for product development, testing and investigational use, and approval. To the best of petitioner's knowledge, no extraordinary circumstances exist, which may significantly affect the human environment as discussed under 21 CFR 25.21.

IV. Economic Impact

An economic impact statement pertaining to (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand has not been prepared for this petition. Richdel will provide such an analysis if so requested by the Commissioner.

V. Identification of Single Listed Pioneer Drug

NADA NO.	NAME OF DRUG	COMPANY	APPROVAL DATE
134-314	Eqvalan®	Merial Ltd.	05/29/1984

VI. Labeling

The following pages provide copies of the proposed generic product labeling and the reference drug labeling.

Differences between the proposed generic product labeling and the pioneer product labeling:

A. Box Front Panel

1. Changed " EQVALAN®" to "Brand Name".
2. Changed "Paste 1.87%" to "Oral Gel 1.87%"
3. Product number will be changed.
4. The statement, "For Sale to Licensed Veterinarians" will be removed.

B. Box Side Panels

1. Panel 1

   a. U. S. patent number is changed to "U.S. Patent Pending."

   b. "EQVALAN® and horse head logo REG TMs MERCK & CO., INC." is removed.

   c. "EQVALAN®" changed to "Brand Name"; horse head logo removed; "Paste 1.87%" changed to "Oral Gel 1.87% "

   d. The drawing of the wrapped syringe and the statement, "Sealed for Security. If broken, do not accept" will be removed and will be replaced with "WARNING" statement.

2. Panel 2

   a. "EQVALAN (ivermectin) Paste" changed to "Brand Name Oral Gel" throughout.

   b. Under "Note to User" the first sentence has been changed from, "Swelling and itching reactions... **have occurred**..." to "Swelling and itching reactions **may occur**..." The second sentence has been changed from, "These reactions **were** most likely..." to "These reactions **are** most likely..."

   c. The "CAUTION" and "Note to User" statements will be reformatted to fit this panel.

C. Box Back Panel

1. "EQVALAN®" and "Paste" have been changed throughout to "Brand Name" and "Oral Gel."

2. The bar code will be different.

3. The sponsor's name and address have been changed to those for Richdel, Inc.

D Oral Gel Syringe Label vs. Paste Syringe Label

4. "EQVALAN" and "Paste 1.87%" are changed throughout to "Brand Name" and "Oral Gel 1.87%."

5. The sponsor's name and address are changed from Merck to Richdel, Inc.

6. Product number will be changed.

VII. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to this petition.

Signature:

Name of Petitioner: Richdel, Inc.

Mailing Address: 23 Industrial Parkway
Moundhouse, NV 89706

Telephone Number: (775) 246-3022

PROPOSED GENERIC DRUG LABELING

BOX FRONT PANEL

BRAND NAME

(ivermectin) **Oral Gel 1.87%**

Anthelmintic and Boticide

Net Wt. 0.21 oz (6.1 g) **Product xxxxx**

Removes worms and bots with a single dose.

Contents will treat up to 1250 lb. body weight

For Oral Use In Horses Only

BOX BACK PANEL

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Brand Name (ivermectin) Oral Gel provides effective control of the following parasites in horses. ***Large Strongyles*** (adults) – *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus, Triodontophorus* spp; ***Small Strongyles*** including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae) – *Cyathostomum spp, Cylicocyclus spp, Cylicostephanus spp, Cylicodontophorus spp,* ***Pinworms*** (adults and fourth-stage larvae) – *Oxyuris equi;* ***Ascarids*** (adults and third- and fourth-stage larvae) – *Parascaris equorum;* ***Hairworms*** (adults) – *Trichostrongylus axei;* ***Large-mouth Stomach Worms*** (adults) – *Habronema muscae;* ***Bots*** (oral and gastric stages)-*Gastrophilus spp;* ***Lungworms*** (adults and fourth-stage larvae)-*Dictyocaulus arnfieldi;* ***Intestinal Threadworms*** (adults)-*Strongyloides westeri;* ***Summer sores*** caused by *Habronema* and *Draschia* spp cutaneous third-stage larvae: Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

DOSAGE AND ADMINISTRATION: This syringe contains sufficient Oral Gel to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each weight marking on the syringe plunger delivers enough ivermectin to treat 250 lb body weight.

(1) While holding plunger, turn the knurled ring on the plunger ¼ turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking. (2) Lock the ring in place by making a ¼ turn to the right. (3) Make sure that the horse's mouth contains no feed. (4) Remove the cover from the tip of the syringe (5) Insert the syringe tip into the horse's mouth at the space between the teeth. (6) Depress the plunger as far as it will go, depositing paste on the back of the tongue. (7) Immediately raise the horse's head for a few seconds after dosing.

PARASITE CONTROL PROGRAM: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. BRAND NAME (ivermectin) Oral Gel effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by *Strongylus vulgaris.*

PRODUCT ADVANTAGES: *Broad-spectrum Control* – Brand Name Oral Gel kills important internal parasites, including bots and the arterial stages of *S. vulgaris,* with a single dose. BRAND NAME is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

Safety – BRAND NAME (ivermectin) Oral Gel may be used in horses of all ages, including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility.

bar code to be added

3 1234-567890 6

Lot No. & Exp. Date

Richdel, Inc.
Moundhouse, NV 89706
U.S.A

BOX SIDE PANELS

WARNING: Do not use in horses intended for food purposes.

U.S. Patent Pending

BRAND NAME

(ivermectin) Oral Gel 1.87 %

Made in U.S.A.

CAUTION: BRAND NAME (ivermectin) Oral Gel has been formulated for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. **Keep this and all drugs out of the reach of children.**

Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

NOTE TO USER: Swelling and itching reactions after treatment with Brand Name (ivermectin) Oral Gel may occur in horses carrying heavy infections of neck threadworm (*Onchocerca* sp) microfilariae. These reactions are most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with Brand Name Oral Gel. Re-infection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

SYRINGE LABEL

Product xxxxx **For Oral Use in Horses Only**

BRAND NAME

(ivermectin) Oral Gel 1.87 %

Anthelmintic and Boticide

For Treatment of Large Strongyles, Small Strongyles, Pinworms, Roundworms (Ascarids), Hairworms, Neck Treadworms, Large-mouth Stomach Worms, Bots. See carton or attached labeling for complete indications and use directions. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Net wt. 0.21 oz (6.1 g) Made in U.S.A.

WARNING: Do not use in horses intended for food purposes.

CAUTION: Refrain from smoking or eating when handling. Wash hands after use. Avoid contact with eyes. **Keep this and all drugs out of the reach of children.**

Lot. No. &
Exp. Date

Richdel, Inc.

Moundhouse, NV 89706
USA

REFERENCE DRUG LABELING

CARTON FRONT PANEL

Eqvalan®

(ivermectin) Paste 1.87%

Anthelmintic and Boticide

Net Wt 0.21 oz (6.08 g)

Product 25874

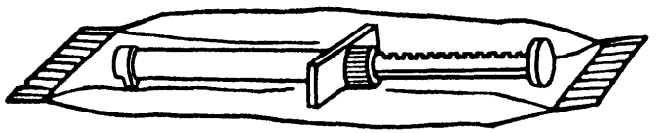
Removes worms and bots with a single dose.

Contents will treat up to 1250 lb body weight

For Oral Use In Horses Only

For Sale to Licensed Veterinarians

CARTON SIDE PANELS



SEALED FOR SECURITY. IF BROKEN, DO NOT ACCEPT.

U.S. Pat. 4,199,569

EQVALAN and Horse Head Logo
REG TMs MERCK & CO., Inc.

Made in U.S.A.

Eqvalan®
(Ivermectin) Paste 1.87%

WARNING: Do not use in horses intended for food purposes.

CAUTION: EQVALAN® (ivermectin) Paste has been formulated specifically for use in horses **only**. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. **Keep this and all drugs out of the reach of children.**

Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

NOTE TO USER: Swelling and itching reactions after treatment with EQVALAN (ivermectin) Paste have occurred in horses carrying heavy infections of neck threadworm (*Onchocerca* sp) microfilariae. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with EQVALAN Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

CARTON BACK PANEL

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PRODUCT ADVANTAGES: ***Broad-spectrum Control***—EQVALAN Paste kills important internal parasites, including bots and the arterial stages of *S. vulgaris*, with a single dose. EQVALAN Paste is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

Safety – EQVALAN (ivermectin) Paste may be used in horses of all ages, including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility.

83938

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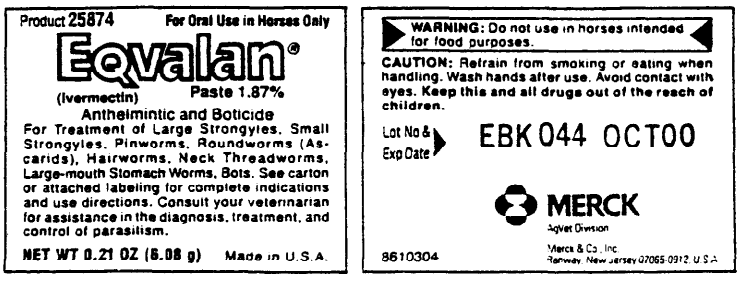
Lot No & Exp Date▼

EBK 044
OCT00

MERCK
AgVet Division

Merck & Co., Inc.
Rahway, New Jersey 07065-0912, U.S.A.

SYRINGE PANEL



CERTIFIED MAIL

7001 0320 0003 2645 7037

Return Receipt Requested

PRIORITY

RM: HFA-305/ RM 1061

FROM:
SERV: CE
TRK#: 70010320000326457O
TO: HFA-305/ RM 1061
05/03/02 11:34
FDA
OF PCS: 1
812302416803 3

PRIORITY

Shotwell Carr & Christensen
3535 Firewheel Dr., Suite A
Flower Mound, Texas 75028

DOCUMENTS MANAGEMENT BRANCH
HFA-305, ROOM 1061
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE
ROCKVILLE, MD 20852